

# Cost Assessment for Oncology Patients: Sodium Bicarbonate 2% Oral Solution Mouth Wash for Mucositis

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## Abstract

**Background:** Chemotherapy induced mucositis is one of the deterring factors influencing adherence to cancer treatment. Sodium bicarbonate mouth wash was recently shown to increase patients' compliance. However, the cost implication of this strategy was never explored. **Aim:** This study is designed to explore the compounding of sodium bicarbonate 2% mouth wash from sodium bicarbonate powder USP and commercially procured intravenous solution, and to determine the estimated cost implication for patients using this strategy. **Materials and Methods:** Sodium bicarbonate 2% were compounded using commercially procured sterile intravenous 8.4% solution and powder USP, diluted and dissolved in sterile water for irrigation respectively. The estimated cost savings between the 2 methods were compared to each other as well as to savings from when used in preventing or in adjuvant therapy for chemotherapy induced mucositis. Ethical approval not required by UVA Institutional Review Board. Study conducted according to the International Standards of Good Practice. **Result:** We came up with a new recipe, sodium bicarbonate 2% mouth wash using commercially procured sterile liquid formulation. Due to shortage, we compounded with sodium bicarbonate powder USP. Using USP 795 regulation, we assigned 14 days beyond use date with refrigeration to these formulations. These formulations resulted in estimated cost savings of \$3597.52 and \$3686.56 respectively if patients were to be treated for chemotherapy induced mucositis for 21 days. When compared to commercially procured sterile liquid formulation, the use of powder USP, will lead to additional estimated 60 to 66.67% savings for patients. **Conclusion:** By using sodium bicarbonate powder or solution to compound a 2% mouth wash, we came up with a cheap product that could be used by patients in the moment in the hospital. We were

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also able to suggest ways that an estimated cost savings for patients undergoing cancer treatment that use this product can be computed.

## Keywords

Mucositis, Sodium Bicarbonate, 2% Mouth Wash, Chemotherapy, USP 795

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## 1. Background

Cancer is one of the diseases that can cause significant infirmity in patients [1]-[21]. Although the treatment of cancer using several modalities has improved patient outcomes over the last decade, side effects associated with chemotherapy remains profound [1]-[21]. The current goals of cancer therapy are to minimize and treat side effects and improve patients' quality of life [1]-[21]. Oral mucositis and ulcerative lesions of the oral mucosa are common side effects observed in some patients undergoing chemotherapy and/or radiation treatment that diminish the patient's quality of life [5] [6] [10] [13]. These lesions are often very painful and compromise oral hygiene as well as increase the risk for local buccal, intestinal and systemic infections [5] [6] [8] [9] [13] [18].

It is important for these incidents to be prevented and treated as the cost of care involving untreated oral mucositis and ulcerative lesions in cancer patients can be prohibitive [6] [14] [17]. Should mucositis and ulcerative lesions occur, this can be a hindrance to patients continuing their cancer therapy. It also has the potential to have a high economic impact for patients because it limits their ability to feed orally [5]-[7] [14] [17] [19]. These patients often must receive costly nutrition through costly intravenous and oral tubing routes [6] [10] [18] [19] [21].

Sodium bicarbonate mouth wash/rinse helps clean, lubricate and buffer the oral environment and also helps prevent the growth of deleterious microorganisms [4] [5] [16] [19] [21]. Thus, it helps to prevent the proliferation of infections in the buccal, intestinal and systemic environment [4] [5] [16] [19] [21]. A prospective cohort study was conducted to evaluate the association between sodium bicarbonate and oral pH [4]. Sodium bicarbonate 6% solution (3 g of sodium bicarbonate powder in 50 mL of water) was given to 25 healthy participants who were instructed to wash/rinse their mouths with the solution [4]. The results demonstrated that rinsing one's mouth with a sodium bicarbonate solution can have a small reduction of bacterial count in the oral cavity [4]. Another randomized controlled trial study was conducted with 144 patients who were diagnosed with cancer and underwent chemotherapy. They were randomized into three groups to receive sodium bicarbonate 5% mouthwash, zinc chloride 0.2% mouthwash, and a placebo [5]. The study found that the sodium bicarbonate and zinc chloride rinse significantly reduced the severity of oral mucositis and improved quality of life as compared to the placebo group [5].

In 2015, we began ordering sodium bicarbonate 2% mouth wash/rinse to reduce

the incidence of oral mucositis in cancer patients. We used commercially procured sterile sodium bicarbonate 1 mEq/mL (8.4%) liquid intravenous (IV) formulation diluted in sterile water for irrigation to prepare a sodium bicarbonate mouthwash 2% (equivalent to 1 g of sodium bicarbonate in 50 mL). Starting October 2016, the commercially procured sterile liquid IV formulation was difficult to obtain due to drug shortages. The mouth wash was alternatively prepared using sodium bicarbonate powder USP, diluted in sterile water for irrigation. We determined the estimated patient cost implication for these strategies.

## 2. Materials and Methods

### 2.1. Ethics Statement

Ethical approval not required by University of Virginia (UVA) Institutional Review Board. Study was conducted according to the International Standards of Good Practice.

### 2.2. Materials

Sterile Sodium bicarbonate solution 8.4% (1 MEQ/ML) 50 ml manufactured by Exela Pharma Sciences LLC, Sodium bicarbonate powder, USP manufactured by HUMCO and Sterile water for irrigation manufactured by Fresenius Kabi LLC were purchased from Cardinal, USA.

### 2.3. Methods

For sodium bicarbonate compounded from commercially procured sterile solution, its required amount and that of sterile water for irrigation were measured and mixed. For sodium bicarbonate compounded from powder USP, its required amount was weighed and that of sterile water for irrigation was measured and mixed. Depending on patient's buccal cavity size, 15 to 30 ml of mouth wash volumes are typically used [12] and as such, we used these volumes in our study. 15 - 30 ml of the final products were aliquoted into appropriate oral cups, beyond use date of 14 days under refrigeration was assigned and final products were labelled.

The treatment regimen that includes fluorouracil (5-FU) and/or irinotecan are known to commonly cause mucositis [13] [14]. For instance, in the treatment protocol for advanced solid tumors, patients do receive irinotecan hydrochloride from 60 to 120 mg/m<sup>2</sup> as a 90-min intravenous infusion on day 1, followed by 24 h infusion of 5-FU 2000 mg/m<sup>2</sup> and leucovorin 200 mg/m<sup>2</sup> on days 1 and 8, every 3 weeks (21 days cycle) [13]. Most institutions including ours, administer mouthwashes every 4 to 6 hours PRN, depending on the severity of mucositis [15] [19]. In the current study, we used every 4 and 6 hours daily over 21 days' time period to estimate patient related cost.

**Estimated cost of using sodium bicarbonate 2% mouth wash every 6 hours (4 times daily) for 21 days period:**

For 30 ml cups:

1) Commercially procured sterile sodium bicarbonate solution for IV: cost of

ingredient (\$1.22) × frequency of administration (4 times daily = \$4.88) × 21 days = \$102.48.

2) Sodium bicarbonate powder USP: cost of ingredient (\$0.16) × frequency of administration (4 times daily = \$0.64) × 21 days = \$13.44.

For 15 ml cups:

1) Commercially procured sterile sodium bicarbonate solution for IV: cost of ingredient (\$0.61) × frequency of administration (4 times daily = \$2.44) × 21 days = \$51.24.

2) Sodium bicarbonate powder USP: cost of ingredient (\$0.08) × frequency of administration (4 times daily = \$0.32) × 21 days = \$6.72.

**Estimated cost of using sodium bicarbonate 2% mouth wash every 4 hours (6 times daily) for 21 days period:**

For 30 ml cups:

1) Commercially procured sterile sodium bicarbonate solution for IV: cost of ingredient (\$1.22) × frequency of administration (6 times daily = \$7.22) × 21 days = \$153.72.

2) Sodium bicarbonate powder USP: cost of ingredient (\$0.16) × frequency of administration (6 times daily = \$0.96) × 21 days = \$20.16.

For 15 ml cups:

1) Commercially procured sterile sodium bicarbonate solution for IV: cost of ingredient (\$0.61) × frequency of administration (6 times daily = \$3.66) × 21 days = \$78.86.

2) Sodium bicarbonate powder USP: cost of ingredient (\$0.08) × frequency of administration (6 times daily = \$0.48) × 21 days = \$10.08.

### 3. Result

#### 3.1. Sodium Bicarbonate Compendium

Sodium bicarbonate mouth washes at 5 and 6% were previously shown to be an effective cheap alternative for the prevention and treatment of chemotherapy induced oral mucositis [4] [5] [19], and as such UVA Health providers sort to order it for the prevention and treatment of oral mucositis among their cancer patients. However, the Australian cancer council in their tips to patients with regards to mouth health during chemotherapy, suggested using 1.5 to 3 grams in 237 ml (0.65% to 1.3%) [16]. Because of this discrepancy in optimal concentration for sodium bicarbonate mouth washes, on March 2015, UVA Health inpatient oncology team started to order sodium bicarbonate mouthwash 2% for patients using the ingredients and preparation shown in **Figure 1**. This is a new formulation with a concentration in-between the currently used formulations (**Figure 1**).

The mouthwash was compounded following USP compounding <795> guideline [11]. It had 1 day beyond-use-date when stored at room temperature and 14 days under refrigeration [11] (**Figure 1**). When Sodium Bicarbonate 1 mEq/mL (8.4%) solution was difficult to obtain due to drug shortage, the mouthwash was compounded using sodium bicarbonate powder USP and sterile water for

irrigation (**Table 1**). The compounded mouthwash was assigned 14 days beyond-use-date (BUD) under refrigeration (**Table 1**) [11].

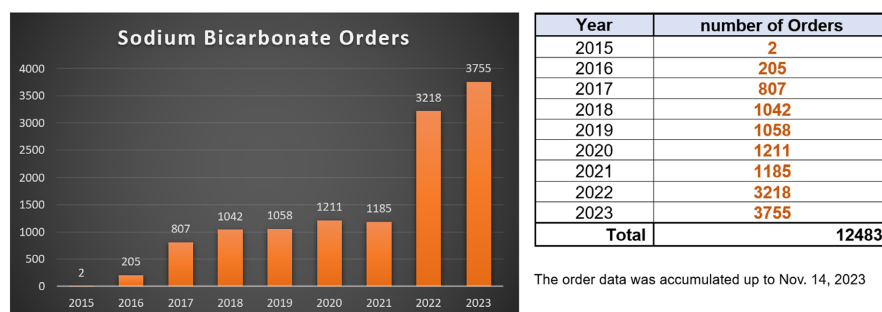
<b>Compound:</b>	Sodium Bicarbonate Mouth Wash 2%	
<b>Concentration:</b>	2%	
<b>Special Handling:</b>	None	
<b>NO.OP.</b>	<b>INGREDIENTS</b>	<b>AMOUNT</b>
1.	Sodium Bicarbonate IV solution 1 mEq/mL (8.4%)	36 ml
2.	Sterile Water for Irrigation	QS AD 114 mL
<b>Total Volume</b>		<b>150 mL</b>

**Figure 1.** Formular for compounding sodium bicarbonate 2% using commercially procured sodium bicarbonate sterile solution (1 mEq/ml) (8.4%).

**Table 1.** Formular for compounding sodium bicarbonate 2% using sodium bicarbonate powder, USP.

<b>Compound:</b>	Sodium Bicarbonate Mouth Wash 2%	
<b>Strength:</b>	2%	
<b>Special Handling:</b>	None	
<b>NO. OP.</b>	<b>Ingredients</b>	<b>Amount</b>
1.	Sodium Bicarbonate powder, USP	9.6 g
2.	Sterile water for irrigation or sterile water for injection QS AD	480 mL
<b>Total Volume</b>		<b>480 mL</b>

Within a short period of time, sodium bicarbonate mouthwash 2% became one of the most frequently ordered oral mouth washes for patients undergoing chemotherapy known to induce mucositis [13]-[15] [19]. The number of Sodium bicarbonate mouthwash orders increased each year from 2 in 2015 to 3755 in 2023 (**Figure 2**). Its use grew immediately during one year period, exploded to 3218 in 2022 and hovering in the high 3000 by mid-2023 (**Figure 2**).



**Figure 2.** Sodium bicarbonate usage over time. From 2015 to November, 14<sup>th</sup>, 2023.

Like previously reported [5] [6] [15], the most frequently ordered frequencies were as needed (PRN) and four times daily (QID) (**Table 2**).

**Table 2.** Frequency of sodium bicarbonate 2% mouth wash usage overtime.

Frequency	Sodium bicarbonate orders
Once	161
PRN	6245
BID	17
TID	39
QID	5895
Daily	3
Q4H	123
<b>Total</b>	<b>12,483</b>

### 3.2. Cost-Benefits Analysis

#### Daily benefits derived from the use of 2% sodium bicarbonate mouth wash

According to a systemic review on direct costs associated with the management of mucositis, the incremental cost of oral mucositis was \$5000 - \$30,000 per patient who received radiation therapy and \$3700 per cycle (21 days) per patient receiving chemotherapy [6] [13]. Each order of sodium bicarbonate mouthwash contains 15 - 30 mL of Sodium bicarbonate 2% solution. The cost of the mouthwash using commercially procured sodium bicarbonate 1 mEq/mL (8.4%) solution as the ingredient is approximately \$0.61 to \$1.22 per order. The cost is approximately \$0.08 to \$0.16 per order if sodium bicarbonate powder was used. This represented 86.9% drop in cost per order (\$1.22 vs \$0.16). The total cost per patient being treated with sodium bicarbonate mouthwash 15 - 30 ml prepared from commercially procured sodium bicarbonate 1 mEq/mL (8.4%) solution or sodium bicarbonate powder four times daily would be \$2.44 to \$4.88 and \$0.32 to \$0.64 respectively. The cost for six times daily is \$3.66 to \$7.32 (15 - 30 ml cups) for commercially procured solution and \$0.48 to \$0.96 (15 - 30 ml cups) for powder USP compounding ingredients respectively.

#### Benefits derived from the use of 2% sodium bicarbonate mouth wash in 21 days cycle

Looking at an example of a patient who received a 21-day cycle of chemotherapy and using 15 - 30 ml of sodium bicarbonate mouthwash four times a day, the net-benefit for oral mucositis prevention will be \$3648.76 and \$3597.52 for sodium bicarbonate mouth wash prepared from 1 mEq/mL (8.4%) IV solution and \$3693.28 and \$3686.56 if the sodium bicarbonate powder is being used (Table 3(A) & Table 3(B)). For six times daily, 15 - 30 ml, net-benefit estimates will be, \$3621.14 and 3546.28 when prepared from 1 mEq/mL (8.4%) IV solution, \$3689.92 and \$3679.84 when prepared from powder USP (Table 3(C) and Table 3(D)). Comparing the two formulations for 4 times daily usage, patients will have additional estimated \$89 (30 ml cups: \$102.48 - \$13.44) and \$44.52 (15 ml cups: \$51.24 - \$6.72) net-savings/benefit, when using the powder form to prepare the mouthwash

(Table 3(A) to Table 3(D)). The additional estimated net-savings/benefit is increased slightly to \$133.56 (30 ml cups: \$153.72 - \$20.16) and \$68.78 (15 ml cups: \$78.86 - \$10.08) for 6 times daily usage (Table 3(A) to Table 3(D)).

**Table 3.** (A) Estimated net-benefit for 30 ml sodium bicarbonate mouth wash for patients receiving 21-day cycle chemotherapy for oral mucositis intervention [6]. Estimation of cost base on usage of sodium bicarbonate mouth wash four times a day. (B) Estimated net-benefit for 15 ml sodium bicarbonate mouth wash for patients receiving 21-day cycle chemotherapy for oral mucositis intervention [6]. Estimation of cost base on usage of sodium bicarbonate mouth wash four times a day. (C) Estimated net-benefit for 30 ml sodium bicarbonate mouth wash for patients receiving 21-day cycle chemotherapy for oral mucositis intervention [6]. Estimation of cost base on usage of sodium bicarbonate mouth wash six times a day. (D) Estimated net-benefit for 15 ml sodium bicarbonate mouth wash for patients receiving 21-day cycle chemotherapy for oral mucositis intervention [6]. Estimation of cost base on usage of sodium bicarbonate mouth wash six times a day. (E) Estimated daily net-benefit for 30 ml sodium bicarbonate mouth wash for patients during hospitalization [17] [20]. We left out the powder formulation, 15 ml, and present here the least savings using the liquid formulation. (F) Estimated net-benefit (Australian dollars: current exchange rate is \$1.58 Australian to \$1 US dollars) for 30 ml sodium bicarbonate mouth wash in patients receiving tube feeding [20]. We left out the powder formulation, 15 ml and present here the least savings using the liquid formulation.

(A)			
Intervention	Benefit per patient	Cost per patient	Net-benefit per patient
Sodium Bicarbonate 1 mEq/mL (8.4%) solution	\$3700	\$102.48	\$3597.52
Sodium Bicarbonate powder	\$3700	\$13.44	\$3686.56
(B)			
Intervention	Benefit per patient	Cost per patient	Net-benefit per patient
Sodium Bicarbonate 1 mEq/mL (8.4%) solution	\$3700	\$51.24	\$3648.76
Sodium Bicarbonate powder	\$3700	\$6.72	\$3693.28
(C)			
Intervention	Benefit per patient	Cost per patient	Net-benefit per patient
Sodium Bicarbonate 1 mEq/mL (8.4%) solution	\$3700	\$153.72	\$3546.28
Sodium Bicarbonate powder	\$3700	\$20.16	\$3679.84
(D)			
Intervention	Benefit per patient	Cost per patient	Net-benefit per patient
Sodium Bicarbonate 1 mEq/mL (8.4%) solution	\$3700	\$78.86	\$3621.14
Sodium Bicarbonate powder	\$3700	\$10.08	\$3689.92
(E)			
Intervention	Benefit per patient	Cost per patient	Net-benefit per patient
Sodium Bicarbonate 1 mEq/mL (8.4%) solution	\$1909	\$7.2	\$1901.8
(F)			

**Continued**

Intervention	Benefit per patient	Cost per patient	Net-benefit per patient
Sodium Bicarbonate 1 mEq/mL (8.4%) solution (NG tube)	\$76	\$7.22	\$68.78
Sodium Bicarbonate 1 mEq/mL (8.4%) solution (PEG tube)	\$736	\$7.22	\$728.78

#### 4. Discussion

The importance of the prevention and treatment of mucositis induced by chemotherapy cannot be overstated with regards to fostering treatment compliance as well as reduction in cost associated with overall cancer treatment [1]-[21]. Recently, several cost-effective interventions were instituted to reduce the burden of chemotherapy induced side effects in patients and to increase compliance to treatment [1]-[21]. When compared to other interventions, sodium bicarbonate mouth wash 5% was shown to be effective in reducing pain associated with mucositis, its incidence as well as severity within 2 weeks [5]. Chandel S *et al.*, and Mohammadi F *et al.*, reported that sodium bicarbonate at 5% to 6% had positive and beneficial effects when used in the prevention or treatment of chemotherapy induced mucositis due to its low cost and is bland in taste associated with no side effects [4]-[6]. In fact, the authors reported that it had better acceptance among patients undergoing chemotherapy in comparison to other mouth washes [4]-[7]. That because of these reasons, it can be used as an adjunct to oral hygiene measures for long periods with more patient comfort during the maintenance phase of chemotherapy [4]-[7]. The authors further reported that sodium bicarbonate mouth wash was easy to prepare implying that patients can prepare by themselves while at home after hospitalization [4]-[7]. Even though Chandel S *et al.*, and Mohammadi F *et al.* stated that the use of sodium bicarbonate mouth wash is an attractive and cost-effective way of preventing as well as treating chemotherapy induced mucositis [4] [5], they did not estimate the cost implication of this strategy [4] [5]. In this study, we pointed out some areas whereby the use of sodium bicarbonate mouth wash could lead to cost benefit for patients.

Because of the advantages presented by Chandel S *et al.*, and Mohammadi F *et al.* with regards to the use of sodium bicarbonate mouth wash, we sort to use in our oncology population. However, with the variation in concentrations of sodium bicarbonate mouth washes that are being currently used (0.68% to 6%) [4] [5] [17] [19], we decided to come up with a concentration that is in-between, *i.e.*, 2%. To our surprise it became a go to mouth wash for providers and acceptable by our patients. We became curious and wondered what the cost-savings/benefit for patients will be. We searched the literature for guidance on the best way to determine this and came across a current study that estimated that patients will save \$3700 if they were mucositis free during 21 days chemotherapy without preventive or treatment interventions [6] [7] [13]. We use this as a reference point for determining the cost-savings/benefit for patients. We determine the estimated

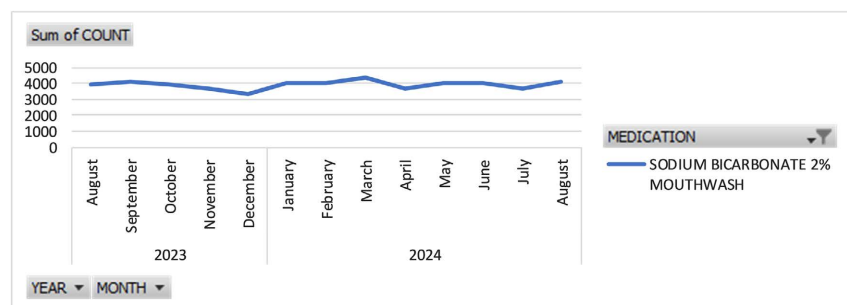
cost implication of using sodium bicarbonate mouth wash in preventing mucositis, specifically one caused by chemotherapy. We used 15 to 30 ml, known standard volumes for washing/rinsing the buccal cavity and estimated the cost-savings/benefit for preventing chemotherapy induced mucositis. We showed that patient will save an estimated \$3597.52 to \$3648.76 when they use sodium bicarbonate mouth wash 2% prepared from sterile commercially procured sodium bicarbonate solution. This will further increase to \$3686.56 to \$3693.28 when prepared from sodium bicarbonate powder USP. In comparison to the 5% to 6% that are used in other hospitals, the 2% in this study contains 60% to 66.67% less sodium bicarbonate and thus provides additional savings for patients [4]-[6] [19].

The development of oral mucositis as a result of chemotherapy does not occur in silos but rather with other side effects and thus underscores the importance of its prevention. In fact, it has been postulated that mucositis as a result of chemotherapy could either proceed or lead to multiple side effects [14] [15] [17] [21]. This includes oral pain, stomatitis, diarrhea, thrombocytopenia, dehydration, vomiting, anemia and neutropenia (cluster side effects). In many cases patients end up getting hospitalized costing \$1909 per day for the cluster of side effects listed above [17]. Considering this, patient using sodium bicarbonate 2% will enjoy an estimated cost-savings/benefit of at least \$1901.78 daily, if they were kept out of the hospital (**Table 3(E)**) [17]. In addition, if one was to stratify and use an example of enteral feeding, it is estimated that percutaneous endoscopic gastrostomy (PEG) and nasogastric (NG) tubes cost patients \$736 and \$76 respectively daily amounting to minimum savings of \$728.78 and \$68.78 (**Table 3(F)**). This means that with hospitalization, the cost associated with mucositis for a 21 days period will be over \$40,000, without factoring in money lost by patient not working. In addition, there is also substantial stress and financial burden on family members and care givers that is difficult to quantify. The good news is that newer agents, biologics, used in the treatment of cancer may present less risk for the development of severe oral mucositis, the bad news is that, the use of conventional chemotherapeutic agents as well radiation therapies (mucositis causing therapies) are not going away any time soon and as such, mucositis will continue to play a role in cost associated with cancer therapy for many years to come [18] [21]. This once again underscores the importance of mucositis prevention with easy to make and cheap interventions like sodium bicarbonate mouth wash.

When compared to other studies [4] [5] [14]-[17] [19], one of the limitations of our study is the lack of a complete analysis of cost associated with mucositis with regards to stratification by different cancer conditions as well as the actual number of days patients spend in the hospital with mucositis. We also relied on previous work done in other centers [5] [7] [15] [17] for our analysis instead of having a full-blown study at our center. This would have given the true picture of the cost implications associated with mucositis for patients today and as such our work should not be interpreted as actual but estimated cost savings and an awareness to the public. It however does not take away the fact that we have been able

to in our way brought to limelight the fact that mucositis substantially adds to the cost of cancer treatment when it occurs. In fact, we have highlighted and raised the importance of the use of cheap interventions like sodium bicarbonate mouth wash to prevent mucositis from occurring and thus reduce cost to patients, who already have to deal with the enormous financial burden of cancer. We hope that other health care providers will learn from this model to develop cheap and practical ways of helping cancer patients deal with cost associated with side effects of chemotherapeutic agents.

A second limitation of our study is the lack of clinical data with regards to the effectiveness of sodium bicarbonate 2% in the prevention and/or treatment of oral mucositis. However, data is been collected at our institution, and we believe similar benefits observed by Chandel S *et al.*, and Mohammadi F *et al.* [4] [5] will be observed with the 2% in this study. This is supported by the fact that the use of sodium bicarbonate 2% by patients undergoing mucositis inducing chemotherapy in our institution has grown exponentially in the past nine years. In fact, in the past year (from September 2023 to September 2024), the usage of sodium bicarbonate 2% skyrocketed to 50,799 cups an equivalent of 4233 cups per month (**Figure 3**).



**Figure 3.** Sodium bicarbonate 2% mouth wash usage over time from August, 2023 to August, 2024 averaging 3907 cups per month (50,799 cups in total for a one-year period).

## 5. Future Research

Our current study has gaps that need to be filled in which we have highlighted some above. In addition, future study should include the determination of effectiveness of sodium bicarbonate 2% alone and in combination with other mouth washes or interventions in the prevention or adjuvant treatment of mucositis. It should also look at actual cost savings by patient in the current economy. This should include length of hospitalization, out of pocket cost, cost to family members, loss of wages and productivity contribution to the economy as well. There needs to be cost benefit stratification by specific chemotherapeutic agents, other interventions like radiation, treatment combination regimens, as well as cancers. Finally, differences in physician choice for when to start using sodium bicarbonate in patient should be looked at as well.

## 6. Conclusion

We took advantage of medication shortage and came up with a new recipe for

compounding sodium bicarbonate mouth wash 2% that is easy to make. We used data from a previous study to present estimated cost-savings/benefit for patients using this mouth wash. We showed an example of how hospitals and health systems can come up practical and cheap ways to help patients.

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## Conflicts of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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